

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION AT DAYTON**

**UNITED STATES ex rel.  
DAVID ANTOON, et al.,**

**Case No. 3:12-cv-027**

**Plaintiffs,**

**Judge Thomas M. Rose**

**-v-**

**CLEVELAND CLINIC FOUNDATION,  
et al.,**

**Defendants.**

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**ENTRY AND ORDER OVERRULING THE ANTOONS' MOTION FOR  
LEAVE TO FILE SECOND AMENDED COMPLAINT (Doc. #62);  
GRANTING THE CLEVELAND CLINIC DEFENDANTS' MOTION TO  
DISMISS ANTOONS' AMENDED COMPLAINT (Doc. #55) AND  
GRANTING INTUITIVE'S MOTION TO DISMISS ANTOONS'  
AMENDED COMPLAINT (Doc. #54)**

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Relator David F. Antoon (“Antoon”) filed a Complaint and Amended Complaint in this matter for his spouse and pro se on behalf of himself. What is first at issue is the Antoons’ Motion for Leave To File Second Amended Complaint. (Doc. #62.) Following the filing of this Amended Complaint, the Antoons obtained the services of an attorney who now wishes to file a second amended complaint to correct the deficiencies in the Amended Complaint filed by Antoon, according to the attorney.

Also pending are Motions To Dismiss, one filed by Defendant Intuitive Surgical, Inc. (“Intuitive”) (doc. #54) and one filed by the Cleveland Clinic Defendants (doc. #55). The Cleveland Clinic Defendants are the Cleveland Clinic Foundation (“CCF”), Delos Cosgrove (“Cosgrove”), Antoinette Covin (“Covin”), Jacek Cywinski (“Cywinski”), Daniel DiCello (“DiCello”), Marc Feldman (“Feldman”), Shelly Frost (“Frost”), Dr. Raj Goel (“Goel”), Howard

Goldman (“Goldman”), J. Michael Henderson (“Henderson”), Dr. Jihad Kaouk (“Kaouk”), Michael Lee (“Lee”), Jan Serkey (“Serkey”) and Kay Tucker (“Tucker”). The Motion for Leave To File Second Amended Complaint and the Motions To Dismiss are all fully briefed and ripe for decision. The request to file a second amended complaint will first be addressed because, if granted, it could render the pending motions to dismiss moot.

The Antoons’ proposed second amended complaint consists of 569 paragraphs covering 116 pages and includes more than 700 exhibits. Therein, the Antoons assert 27 causes of action. The Antoons’ first cause of action is against the CCF Defendants<sup>1</sup> and Intuitive for violation of the False Claims Act (“FCA”), 31 U.S.C. § 3729 et seq. The remaining 26 causes of action are brought pursuant to state law or must first be adjudicated in a state court.<sup>2</sup> Finally, this Court’s subject-matter jurisdiction over the Antoons’ proposed second amended complaint is based upon this Court having federal-question jurisdiction.

The only federal question raised in the proposed second amended complaint is a violation of the FCA. Thus, if the FCA claim fails, this Court may not have subject matter jurisdiction.

#### **RELEVANT FACTUAL ALLEGATIONS FROM PROPOSED SECOND AMENDED COMPLAINT**

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<sup>1</sup>The proposed second amended complaint does not identify who are the “CCF Defendants” as alleged in the First Cause of Action.

<sup>2</sup>The Twenty-Fourth Cause of Action, as best this Court can determine, is for a declaratory judgment that Ohio’s “Medical Malpractice Acts” and “Tort Reform Act” are unconstitutional. This declaratory judgment must first be sought in an Ohio court.

The Twenty-Fifth Cause of Action is for a declaratory judgment that the named defendants are not entitled to any set-off from any non-named party and that the named Defendants cannot establish late affirmative defenses or otherwise attempt to shift liability. This, of course, is not a federal question but is an issue for whatever court, if any, may be adjudicating the remainder of Antoons’ assertions.

The following alleged facts are taken from the proposed second amended complaint. They are accepted as true for purposes of evaluating whether the proposed second amended complaint would be futile.

David Antoon was diagnosed with invasive prostate cancer in November of 2007. (Proposed second amended compl., doc. #62-1, ¶¶ 34, 39.) He met with Kaouk, Goel and physician's assistant Brandon Mooney ("Mooney") at the Cleveland Clinic on December 6, 2007, to discuss treatment options. (Id. at ¶¶ 45-59.) After discussing the options, Kaouk scheduled Antoon for surgery on January 8, 2008, and verbally agreed that he would perform the surgery. (Id. at 59.) Antoon signed a consent document on which he wrote, "only Jihad Kaouk is authorized to perform my surgery." (Id.)

Antoon had surgery on January 8, 2008, which he asserts resulted in complications. (Id. at ¶¶ 63-80.) He never saw Kaouk in the operating room before or during his surgery. (Id. at ¶ 65.)

After the surgery, Kaouk told Antoon's wife that he "got stuck," which Kaouk later explained meant that "it took him more time to get the bowel adhesions down" during the surgery than he had anticipated. (Id. at ¶ 71.) Kaouk also told Antoon that he expected Antoon to fully recover. (Id.) After this surgery, Antoon suffered soaking night sweats, incontinence and impotence. (Id. at ¶¶ 78-80, 83-95.)

On February 5, 2008, Kaouk and CCF submitted "Health Insurance Claim Form 1500" to the U.S. Government for reimbursement for services provided to Antoon. (Id. at 81.) Kaouk signed this claim form certifying that statements on the reverse apply to this bill and are made a part thereof. (Id. at 82.) One such statement on the back is as follows:

I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations." (Id. at ¶ 82.)

On June 19, 2008, Antoon and his wife met with Kaouk and Mooney to discuss Antoon's lack of recovery, incontinence and impotence. (Id. at ¶ 96.) At that time, Kaouk suggested that Antoon remain positive and patient and suggested that Antoon's lack of recovery was anxiety related. (Id.)

In the second half of 2008, Antoon sent emails and made calls to, among others, Kaouk, Mooney and Tucker, most of which were not returned. (Id. at ¶¶ 99-102, 104-24.) Also, on October 1, 2008, Kaouk called Antoon and again encouraged Antoon to be positive and hopeful. (Id. at ¶ 103.) When asked by Antoon if he had performed the surgery, Kaouk responded, "Oh yeah, I remember."

On December 11, 2008, Antoon and his wife again met with Kaouk. (Id. at ¶ 125.) At the time, Kaouk stated that Antoon did not have adhesions and that Kaouk "probably placed clamps on Antoon's nerves." (Id.)

In January and February of 2009, Antoon sent more emails to Kaouk, most of which were not returned. (Id. at ¶¶ 127-31.) Their communications ceased in February of 2009. (Id. at ¶ 131.) Also in February of 2009, Antoon requested all of his medical records from CCF. (Id. at ¶ 132.) The records were provided in piecemeal fashion. (Id.) However, an "informed consent" document was missing from all of the records provided to Antoon at the time but was later provided on January 12, 2010. (Id. at ¶¶ 135, 140.)

One record, dated January 8, 2008, states that Kaouk was present for the critical portions

of the surgery. (Id. at ¶ 143.) This record was not provided to Antoon until 2010. (Id.)

Another record required by the Joint Commission, a private accreditation agency, failed to list Kaouk as the doctor. (Id. at ¶ 144.) Various other records fail to show all events of the surgery and the following days. (Id. at ¶¶ 147-61.)

In July of 2009, Antoon contacted the CCF Ombudsman's office, and DiCello investigated his concerns. (Id. at ¶¶ 166-68.) Ultimately, DiCello told Antoon that his investigation revealed that Antoon's surgery fell within the standard of care for such surgeries and denied Antoon's request for \$975,000. (Id. at 174, Ex. 32.)

In August of 2009, Antoon filed a complaint with the Joint Commission. (Id. at ¶¶ 178-79.) The Joint Commission closed this case in December of 2010, noting that CCF had taken Antoon's concerns seriously and had initiated a proper response. (Id. at ¶ 179, Ex. 12.) Antoon continues to file complaints with the Joint Commission. (Id. at 203, Ex. 683.)

Also in August of 2009, Antoon filed the first of several complaints with the Ohio Department of Health ("ODH"). (Id. at ¶ 180.) The ODH told him that the Centers for Medicare/Medicaid Service ("CMS") regulates hospitals and had not authorized an investigation. (Id.) In November of 2009, a CMS official told Antoon that it had authorized the ODH to investigate because Antoon's allegations suggested "that there might be a violation of Federal regulation (Conditions of Participation for Hospitals) if substantiated." (Id. at Ex. 6.)

Antoon has filed 41 Freedom of Information Act ("FOIA") requests to CMS, 38 to DOD/TRICARE and 7 to the U.S. Department of Health and Human Services ("HHS"). (Id. at ¶ 202.) As a result, Antoon received both the CMS report from the investigation and CCF's response. (Id. at Ex. 8.) The investigation determined that there had been violations of Medicare

conditions of participation, including failing to adequately respond to Antoon's inquiries and to keep proper records. (Id. at ¶ 193, Ex. 8.) But CMS found Antoon's claim that Kaouk did not perform his surgery to be unsubstantiated. (Id. at Ex. 8.)

Antoon also received the results of five (5) investigative surveys performed by CMS. (Id. at ¶ 196.) Each survey resulted in citations of serious violations of CMS Conditions of Participation, Standards, and Requirements. (Id.)

In late 2009 and early 2010, Antoon complained to several other entities. He complained to the State Medical Board of Ohio against Kaouk. (Id. at ¶ 181.) This complaint was later dismissed without action. (Id.) An appeal was denied but later reopened and remains active. (Id.)

Antoon also filed complaints with the State Medical Boards of Utah, Indiana and Iowa. (Id. at 276.) Utah deferred jurisdiction to Ohio and said it will take reciprocal action. (Id. at ¶ 225.) The investigation by the State Medical Board of Indiana remains active. (Id. at ¶ 271.) The Iowa Board of Medicine indicated that Kaouk did not meet their requirements and that Kaouk's claim of licensure in Iowa was false. (Id. at ¶ 272.)

Antoon also complained to Healthnet Federal Services, a private company that processes TRICARE claims. (Id. at 186.) In addition, he asked Blue Cross Blue Shield to investigate. (Id. at 187-90.) Finally, Antoon complained to the Office of Civil Rights within HHS about alleged violations of medical-records laws. (Id. at ¶ 198.)

In February of 2010, Antoon and his spouse filed their first *qui tam* suit. (Id. at 200.) This case was filed in the Southern District of Ohio and was dismissed on November 29, 2010 for want of prosecution. *Antoon v Cleveland Clinic Foundation*, et al., No. 3:10-cv-045 (S.D. Ohio). The Complaint in the 2010 case is not sealed. On June 6, 2010, the Antoons filed their original

medical malpractice claim in Cleveland, Ohio. (Id. at 223.)

On December 25, 2011, Antoon filed a complaint with the Department of Defense (“DOD”) Office of the Inspector General (“OIG”). (Id. at 261.) He received no response. (Id.)

On January 1, 2012, Antoon filed a complaint with the HHS OIG alleging fraud. (Id. at ¶ 262.) He received no response. (Id.)

On January 18, 2012, Antoon filed complaints with the United States Department of Justice (“DOJ”) and CMS Office of General Counsel. (Id. at 263.) CMS deferred to DOJ who investigated. (Id.)

On January 31, 2012, the Antoons filed the original Complaint in this case. (Doc. #1.) On May 8, 2012, they filed an Amended Complaint in this case. (Doc. #4.)

Regarding Defendant Intuitive, paragraph 26 of the proposed amended complaint asserts that Intuitive is the owner, inventor, developer, distributor, training source and is responsible for the instruction, maintenance, training, guidelines for use and safe utilization of its robotic machine known as the “da Vinci,” and all related equipment, procedures (“Veil of Aphrodite”) used with the device. Antoon had robotic surgery using the “Veil of Aphrodite” procedure. (Id. at ¶ 46.)

The section of the proposed second amended complaint entitled “Notice of Claims and of Filings, Evidence and Facts in Support of Claims” and the additional section entitled, in part, “Further Facts, Other Investigations and Evidence...” go from paragraph 34 to 277 and do not mention Intuitive. Finally, Intuitive is named in Count 1 for violation of the FCA and is named in fourteen (14) state law claims.

All Defendants moved to dismiss the Amended Complaint. (Docs. # 54 and 55.) The

Antoons responded and moved to file a second amended complaint. (Docs. #60-65.) It is this Motion for Leave To File Second Amended Complaint that is now before the Court. (Doc. #62.)

## **RELEVANT LEGAL PROVISIONS**

### **Motion To Amend**

The Antoons bring their Motion for Leave To Amend pursuant to Fed. R. Civ. P. 15(a)(2). Rule 15(a)(2) provides that leave to amend is to be freely given when justice so requires. *Riverview Health Institute LLC v. Medical Mutual of Ohio*, 601 F.3d 505, 520 (6th Cir. 2010). However, a motion for leave to amend may be denied where there is undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment or futility of amendment. *Id.* A proposed amendment is futile if the amendment could not withstand a motion to dismiss pursuant to Rule 12(b)(6). *Id.* (citing *Rose v. Hartford Underwriters Insurance Co.*, 203 F.3d 417, 420 (6th Cir. 2000)).

### **Motion To Dismiss Pursuant To Fed. R. Civ. P. 12(b)(6)**

The purpose of a Rule 12(b)(6) motion to dismiss is to allow a defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even if everything alleged in the complaint is true. *Mayer v. Mylod*, 988 F. 2d 635, 638 (6th Cir. 1993)(citing *Nishiyama v. Dickson County, Tennessee*, 814 F.2d 277, 279 (6th Cir. 1987)). Put another way, “the purpose of a motion under Federal Rule 12(b)(6) is to test the formal sufficiency of the statement of the claim for relief; the motion is not a procedure for resolving a contest between the parties about the facts or the substantive merits of the plaintiff’s case.” 5B Charles Alan Wright and Arthur R. Miller, *Federal Practice and Procedure* § 1356 (3d ed. 2004). Further, for purposes of a motion

to dismiss, the complaint must be construed in a light most favorable to the plaintiff and its allegations taken as true. *Scheuer v. Rhodes*, 416 U.S. 232 (1974).

To survive a 12(b)(6) motion to dismiss, a plaintiff must provide more than labels and conclusions, and a formulaic recitation of the elements of a cause of action is not enough. *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1964-65 (2007)(citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). “[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint.” *Id.* at 1969. However, the factual allegations must be enough to raise a right to relief above the speculative level. *Id.* at 1965(citing 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, p. 235-236 (3d ed. 2004)). The factual allegations in the complaint, even if doubtful in fact, must do something more than merely create a suspicion of a legally cognizable right. *Id.*

The Sixth Circuit has noted that to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), “a ... complaint must contain either direct or inferential allegations respecting all the material elements to sustain a recovery under *some* viable legal theory.” *Columbia Natural Resources, Inc. v. Tatum*, 58 F. 3d 1101 (6th Cir. 1995), cert. denied, 516 U.S. 1158 (1996). The Court “need not accept as true legal conclusions or unwarranted factual inferences.” *Morgan v. Church’s Fried Chicken*, 829 F. 2d 10, 12 (6th Cir. 1987). Put another way, bare assertions of legal conclusions are not sufficient. *Lillard v. Shelby County Bd. of Education.*, 76 F. 3d 716, 726 (6<sup>th</sup> Cir. 1996). It is only well-pleaded facts which are construed liberally in favor of the party opposing the motion to dismiss. *Id.*

In evaluating whether the plaintiff has stated a cognizable claim, the court generally may not consider matters outside of the pleadings. See *Hammond v. Baldwin*, 866 F.2d 172, 175 (6th

Cir. 1989). To this effect, Rule 12(b) provides that if "matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Fed R. Civ. P. 12(b).

The courts have clarified the scope of what may be considered without reaching "matters outside of the pleadings." A court may consider: (1) any documents attached to, incorporated by or referred to in the pleadings; (2) documents attached to the motion to dismiss that are referred to in the complaint and are central to the plaintiff's allegations, even if not explicitly incorporated by reference; and (4) matters of which the court may take judicial notice. *Apex Energy Group, LLC v. Apex Energy Solutions of Cincinnati, LLC*, No. 1:12cv46, 2013 WL 394464 at \*2 (S.D. Ohio Jan. 31, 2013.) Specifically, a court may take judicial notice of another court's opinion, not for the truth of the facts therein, but for the existence of the opinion. *Winget v. JP Morgan Chase Bank, N. A.*, 537 F.3d 565, 576 (6th Cir. 2008). Under these circumstances, the court may consider extraneous documents without requiring the conversion of the motion to one for summary judgment. *Id.*

Notwithstanding, the ability of a court to consider supplementary documents is not without limitations. The Sixth Circuit has explained that "[w]hile documents integral to the complaint may be relied upon, even if they are not attached or incorporated by reference, it must also be clear that there exist no material disputed issues of fact regarding the relevance of the document." *Mediacom Southeast LLC v. BellSouth Telecommunications., Inc.*, 672 F.3d 396, 400 (6th Cir. 2012) (citations, internal quotation marks, and alterations omitted). Put otherwise, if the authenticity, validity, or enforceability of a document is not in dispute, the court may consider it

on a motion to dismiss; but a genuine dispute as to the legal sufficiency of said document requires the court to consider the issue under a motion for summary judgment standard. *Id.*; *see also* *Ouwinka v. Benistar 419 Plan Services, Inc.*, 694 F.3d 783, 796-797 (6th Cir. 2012).

### **Supplemental Jurisdiction**

The Amended Complaint includes two federal claims and several allegations based upon Ohio law. The proposed second amended complaint includes one federal claim and 26 causes of action based upon Ohio law. Therefore, if all of the federal claims are determined to be futile in either the Amended Complaint or the proposed second amended complaint, the Court must consider whether to exercise supplemental jurisdiction over the remaining state-law claims.

Title 28 U.S.C. § 1367 grants a court broad discretion to decide whether to exercise jurisdiction over state-law claims that are “so related to claims in the action within such original jurisdiction that they form part of the same case or controversy.” *Gamel v. City of Cincinnati*, 625 F.3d 949, 951 (6th Cir. 2010)(quoting 28 U.S.C. § 1367(a)). A court may decline to exercise supplemental jurisdiction where the remaining claims raise a novel or complex issue of State law, where the remaining claims substantially predominate over the claim over which the court has original jurisdiction, where the district court has dismissed all claims over which it has original jurisdiction or where there are compelling reasons for declining jurisdiction. *Williamson v. Recovery Limited Partnership*, No. C2-06-292, 2009 WL 649841 at \*7 (S.D. Ohio Mar. 11, 2009).

When deciding whether to exercise supplemental jurisdiction, the court considers the values of judicial economy, convenience, fairness and comity. *Gamel*, 625 F.3d at 952. A court may also consider whether the plaintiff has engaged in any manipulative tactics when it decides

whether to remand a case. *Id.* at 951. However, when all federal claims are dismissed before trial, the balance of considerations usually will result in dismissal of the state-law claims or remand to state court if the action was removed. *Id.*

### **False Claims Act**

The Antoons bring claims pursuant to the FCA. Relevant provisions of the FCA are set forth below.

#### **FCA Claims**

The FCA creates civil liability for any person who “knowingly presents, or causes to be presented” to the Government “a false or fraudulent claim for payment or approval.” *United States ex rel. Hobbs v. Medquest*, 711 F.3d 707, 713 (6th Cir. 2013)(quoting 31 U.S.C. § 3729(a)(1)). To establish a prima facie FCA violation under this section, a plaintiff must prove that: (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 304-05 (3d Cir. 2011).

Civil liability is also created for any person who knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government. *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011)(citing 31 U.S.C. § 3729(a)(2)). To establish a prima facie FCA violation under this section a plaintiff must prove: (1) the defendant made, used or caused to be made or used, a record or statement to get a claim against the United States paid or approved: (2) the record or statement and the claim were false or fraudulent; (3) the defendant knew that the record or statement and the claim were false or

fraudulent; and (4) the United States suffered damages as a result. *United States ex rel. Morris v. Crist*, No. C-2-97-1395, 1998 U.S. Dist. LEXIS 23402 at \*11 (Oct. 22, 1998).

In addition, civil liability is created for any person who conspires to commit a violation of subparagraphs (A), (B), (D), (E), (F) or (G) of 31 U.S.C. § 3729(a). Subparagraphs D, E and F are not relevant nor discussed here.

Finally, the FCA creates civil liability for any person who knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government (known as the “reverse false claims provision”). *Chesbrough*, 655 F.3d at 466 (citing 31 U.S.C. § 3729(a)(7), now 31 U.S.C. § 3729(a)(G)).

The FCA requires that the false or fraudulent claim be presented by a person with actual knowledge of the information submitted and who acts in deliberate ignorance or with reckless disregard as to the veracity of that information. *Id.* An FCA lawsuit may be filed directly by the Government or, as here, as a *qui tam* action in which the suit is brought by an individual on behalf of the Government and the Government may intervene. *Hobbs*, 711 F.3d at 714.

### **False Certification**

In addition to obvious cases of fraud, such as where a provider bills for procedures or services that were not rendered or not necessary, a claim may be false under a “false certification” theory. *Id.* False certification occurs when a claimant knowingly falsely certifies that it has complied with a statute or regulation, the compliance with which is a condition for Government payment. *Id.* The focus is on the underlying contracts, statutes or regulations themselves to

determine whether they make compliance a prerequisite to the Government's payment. *Id.* The success of a "false certification" claim depends upon whether it is based upon conditions of participation, which does not support an FCA claim, or on conditions of payment, which does support an FCA claim. *Id;* see also *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 532 (6th Cir. 2012).

For example, there is no FCA liability for failure to comply with the supervising-physician regulations because they are conditions of participation. *Id.* at 710. The applicable regulations set forth three levels of supervision: general, direct and personal. *Id.* at 716. General supervision means that the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required. *Id.* Direct supervision requires a physician to be present in the office suite and available to furnish assistance but does not necessarily require the physician to be in the room where the procedure is performed. *Id.* Finally, personal supervision means that a physician must be in attendance in the room during the performance of the procedure. *Id.*

False certification may be express or implied. *Id.* at 714. Under an express false certification, the defendant is alleged to have signed or otherwise certified to compliance with some law or regulation on the face the claim submitted. *Id.* Under an implied false certification, a facially truthful claim may be found to be false if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned. *Id.* Implied false certification is to be applied only when the underlying statute or regulation expressly states that the provider must comply in order to be paid. *Mikes*, 274 F.3d at 700.

### **Medicare Claims**

Medicare statutes and regulations define the requirements for Medicare claims and

underlay the Antoons' FCA claims in this case. *Id.* at 710. Medicare Part B covers the costs of physicians' services, supplies and tests. It covers only tests that are "reasonable and necessary."

*Id.*

Medicare requires entities that seek reimbursement to first enroll and gain approval from their local Medicare carrier. *Id.* A carrier is the claims-processing and claims-regulating entity that contracts with the Centers for Medicare and Medicaid Services ("CMS"), the entity created by the U.S. Department of Health and Human Services ("HHS") to administer the Medicare program. *Id.*

The submission of HCFA-1500 forms is required by the Medicare implementing regulations. *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001). Each submission of the HCFA-1500 or an electronic equivalent meets the first two elements of an FCA cause of action because it qualifies as a claim made to the United States Government. *Id.*

### **The Anti-Kickback Statute**

To be eligible for payment under the Medicare program, providers and suppliers must certify that they understand that payments of claims are conditioned on the claims and the underlying transactions complying with applicable laws, including the Anti-Kickback Statute. *United States ex rel. McDonough v. Symphony Diagnostic Services, Inc.*, No. 2:08-CV—114, 2012 WL 628515 at \*1 (S.D. Ohio Feb. 27, 2012)(citing 42 U.S.C. § 1320a-7b(b)(1)(A)). The Anti-Kickback Statute is part of the Medicare and Medicaid Patient Protection Act. *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 694 F. Supp.2d 48, 51 (D. Mass. 2010), *rev'd on other grounds*, 647 F.3d 377 (1<sup>st</sup> Cir. 2011).

The Anti-Kickback Statute prevents an entity from offering "any remuneration, including

any kickback, bribe or rebate, in return for referring an individual for service for which payment may be made in whole or in part under a Federal health care program. 2012 WL 628515 at \*5 (citing 42 U.S.C. § 1320a-7b(b)(1)(A)). Further, indirect remuneration schemes which involve offers of discounted services in exchange for patient referrals may violate the Anti-Kickback Statute. *Id.* at \*7.

The Anti-Kickback Statute is a criminal statute that provides for criminal penalties. 42 U.S.C. § 1320a-7b. However, federal law also provides for civil monetary penalties for violation of certain provisions of the Anti-Kickback Statute. 42 U.S.C. § 1320a-7a(a)(7).

### **The Public Disclosure Provision**

One jurisdictional limitation on qui tam actions is the public disclosure provision. *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 507 (6th Cir. 2009). The public disclosure provision removes federal jurisdiction from FCA actions that are based upon the public disclosure of allegations or transactions in a criminal, civil or administrative hearing; in a congressional, administrative or Government Accounting Office report, hearing, audit or investigation; or from the news media unless the action is brought by the Attorney General or the person bringing the action is an original source.<sup>3</sup> *Id.*; see also *Schindler Elevator Corp. v. United States ex rel. Kirk*, 131 S. Ct. 1885, 1891 (2011). Public disclosure also includes documents that have been filed with a court, such as discovery documents and a plaintiff's complaint. *Id.* at 512. Also, written FOIA responses, along with their attached records are considered public disclosures. *Schindler Elevator*, 131 S. Ct. at 1893. Finally, a private suit is based upon a public disclosure when the allegations

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<sup>3</sup>The relator has the burden of establishing a court's subject matter jurisdiction over the relator's FCA claim. *Poteet*, 552 F.3d at 510.

are substantially similar to the public disclosure, even if the relator adds details. *United States ex rel. Goldberg v. Rush University Medical Center*, 680 F.3d 933, 934 (7th Cir. 2012).

### **Original Source Exception To Public Disclosure Provision**

There is an exception to the public disclosure provision termed the “original source” exception. *Poteet*, 552 F.3d at 511. The FCA defines an original source as an “individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.” *Id.* (citing 31 U.S.C. § 3730(e)(4)(A)). Thus, to qualify as an original source, the relator not only must discover the fraud independently, but also must disclose it to the Government before filing suit. *Goldberg*, 680 F.3d at 934.

### **Pleading FCA Claims With Particularity**

FCA claims must comply with Fed. R. Civ. P. 9(b). *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 502 (6th Cir. 2008). Rule 9(b) adds additional pleading requirements for allegations of fraud or mistake. *Id.* at 503. Thus, under Rule 9(b), a plaintiff must allege the time, place and content of the alleged misrepresentation, the fraudulent scheme, the fraudulent intent of the defendants and the injury resulting from the fraud. *Id.* at 504. Therefore, a qui tam case may proceed to discovery if the relator’s complaint pleads a complex and far-reaching fraudulent scheme with particularity and provides examples of specific false claims submitted to the Government pursuant to that scheme. *Id.* at 507. However, Rule 9(b) exempts allegations of malice, intent, knowledge and other conditions of a person’s mind from its heightened pleading standards. *Id.* at 509. Also, where a corporation is the defendant, a relator need not always allege the specific identity of the natural persons within the defendant

corporation that submitted the false claim. *United States ex rel. Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 509 (6th Cir. 2007).

#### **ANALYSIS OF MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT**

The FCA claim in the Antoons' proposed second amended complaint will be analyzed first because it may provide this Court with original jurisdiction over the entire proposed second amended complaint. In the proposed second amended complaint, the Antoons allege that the Defendants violated the FCA when they presented false or fraudulent claims under the TRICARE and TRICARE/CHAMPUS programs for payment while not being entitled to participate due to violations of the conditions of participation. They also allege that the Defendants presented false or fraudulent claims for payment under the Medicare and/or Medicaid programs due to violations of the conditions of participation. Finally, the Antoons allege that Intuitive paid remuneration to Kaouk in return for recommending a service for which payment was made in whole or in part by TRICARE and/or by Medicare or Medicaid.

The Cleveland Clinic Defendants argue that the FCA claim against the Cleveland Clinic Defendants in the Antoons' proposed second amended complaint is futile for three reasons. First, the FCA claim in the proposed second amended complaint relies on conditions of participation. Second, this Court's jurisdiction over the FCA claim in the proposed second amended complaint is barred by the public-disclosure provision in the FCA. Third, the proposed second amended complaint belongs in state court.

Intuitive argues that the FCA claim against Intuitive in the proposed second amended complaint is futile because the FCA allegation against Intuitive lacks the specificity required by Rule 9(b) and the plausibility required by Rule 8(a). Intuitive also argues that this Court's

jurisdiction over the FCA claim in the proposed second amended complaint is barred by the public-disclosure provision in the FCA. Finally, Intuitive argues that the conspiracy assertion against it in the proposed second amended complaint is futile because no falsity is alleged and the conspiracy is not alleged with the requisite particularity.

Each of the issues identified by the Cleveland Clinic Defendants and Intuitive will be, if necessary, addressed seriatim.

### **Basis for FCA Claims**

The Antoons' proposed second amended complaint asserts two bases upon which the FCA claim rests: (1) violation of conditions of participation and (2) violation of the Anti-Kickback statute.

A false certification claim, such as the Antoons', based upon violation of conditions of participation is not supported by the FCA. Thus, the Antoons' FCA claim in the proposed second amended complaint based upon alleged violations of conditions of participation is futile.

However, certification of compliance with the Anti-Kickback Statute is a condition of payment and may, therefore, be actionable under the FCA. In the proposed second amended complaint, the Antoons allege that Intuitive violated the Anti-Kickback Statute. However, the Antoons do not allege that Intuitive falsely certified that it had complied with the Anti-Kickback Statute. Thus, the Antoons have made no false certification claim against Intuitive.

The Antoons argue that the proposed second amended complaint alleges an FCA conspiracy between Kaouk and others, including Intuitive, to violate the Anti-Kickback Statute. The proposed second amended complaint alleges that Kaouk and CCF submitted a "Health Insurance Claim Form 1500" to the U.S. Government for reimbursement for services provided to

Antoon. On that form, Kaouk and CCF were required to certify compliance with the Anti-Kickback Statute as a condition for payment. Thus, the proposed second amended complaint may allege that Intuitive, Kaouk and CCF conspired to submit an actionable false claim by violating the Anti-Kickback Statute.

The Anti-Kickback Statute provides for criminal penalties. As a criminal statute, it may not be enforced in a civil matter. However, federal law provides for a civil monetary penalty for violation of the applicable provisions of the Anti-Kickback Statute. 42 U.S.C. § 1392a-7a(a)(7). Thus, a violation of the Anti-Kickback Statute by Kaouk, CCF and Intuitive could be enforced in a civil proceeding. Therefore, the Antoons' allegation that Kaouk, CCF and Intuitive violated the Anti-Kickback statute may be a basis for a civil suit.

In sum, the Antoos' proposed second amended complaint identifies an FCA violation that Kaouk, CCF and Intuitive allegedly conspired to violate, by violating the Anti-Kickback Statute which may be actionable in this civil lawsuit. However, there is no FCA claim remaining against the other Defendants. Next, the Court must consider whether the FCA violation that Kaouk, CCF and Intuitive conspired to violate the FCA is plausibly pled and pled with the required specificity.

#### **Specificity and Plausibility**

The Antoos' remaining FCA claim must be pled with the required specificity in accordance with Rule 9(b). The alleged false claim is the submission of the "Health Insurance Claim Form 1500" to the U.S. Government for reimbursement for services provided to Antoon.

A false claim forming the basis of an FCA allegation must be pled with particularity. Thus, the Antoos must allege the time, place and content of the alleged misrepresentation, the

fraudulent scheme, the fraudulent intent of the defendants and the injury resulting from the fraud.

This the Antoons have done. (See proposed second amended compl., doc. #62-1, ¶ 284.)

The proposed second amended complaint alleges that Kaouk and CCF submitted a "Health Insurance Claim Form 1500" to the U.S. Government on February 5, 2008, for reimbursement for services provided to Antoon. (Id. at ¶ 81.) The reverse side of this Form 1500 includes a notice that any person who knowingly files a statement of claim containing any act punishable under law may be subject to civil penalties. (Id. at ¶¶ 82, 287.)

The basis for the Antoons' remaining FCA claim is violation of the Anti-Kickback Statute. Thus, the Antoons must at least plausibly plead a violation of the Anti-Kickback Statute. The proposed amended complaint discusses kickbacks at only two locations.

Paragraph 303 of the proposed amended complaint is as follows:

Pursuant to 42 U.S.C. § 1320, the Cleveland Clinic Defendants knowingly and willfully received remuneration directly or indirectly, overtly or covertly, in cash or in kind in return for recommending a service for which payment was made in whole or in part by TRICARE and/or by Medicare or Medicaid in connection with David Antoon's surgery and others.

Paragraph 304 of the proposed amended complaint reads as follows:

Pursuant to 42 U.S.C. § 1320, Defendant Intuitive knowingly and willfully paid remuneration directly or indirectly, overtly or covertly, in case or in kind to Kaouk in return for recommending a service for which payment was made in whole or in part by TRICARE and/or by Medicare or Medicaid. Further, Defendant Intuitive knew about and participated in the misconduct of the Cleveland Clinic Defendants as set forth above.

Giving the Antoons the benefit of the doubt, they are presumably referring to the Anti-Kickback statute, 42 U.S.C. § 1302a-7b(b)(2)<sup>4</sup>, which provides that:

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<sup>4</sup>Title 42 of U.S.C. § 1320a-7a(a)(7) provides for civil monetary penalties for violation of 42 U.S.C. § 1320a-7b(b)(2).

whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person... to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arranged for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

Thus, as can be seen above, the proposed amended complaint merely paraphrases the Anti-Kickback Statute. As such, these paragraphs in the proposed amended complaint are legal conclusions and are unsupported by any additional facts. Therefore, violation of the Anti-Kickback Statute is not pled with the required plausibility. Since the proposed amended complaint does not plead violation of the Anti-Kickback Statute with the required plausibility, violation of the Anti-Kickback Statute cannot serve as a basis for the FCA claim, and the FCA claim is futile.

#### **Supplemental Jurisdiction Over State Claims**

Only the federal claim for violation of the FCA provides this Court with original subject-matter jurisdiction to adjudicate the proposed second amended complaint. As more fully set forth above, the FCA claim in the proposed second amended complaint is futile and would be subject to dismissal pursuant to Fed. R. Civ. P. 12(b)(6).

When all federal claims are dismissed before trial, the balance of considerations usually will result in dismissal of the state-law claims. That would be the case here. If the proposed second amended complaint were filed, the Antoons' federal claim would be dismissed and the Court would exercise its discretion to dismiss the state-law claims.

#### **Conclusion On Motion for Leave To File Second Amended Complaint**

The proposed second amended complaint includes only one federal claim, an alleged violation of the FCA. However, this claim would be futile because it would not survive a Rule 12(b)(6) motion to dismiss, and the Court would decline to exercise supplemental jurisdiction over the remaining state-law claims. Therefore, the Antoons' Motion for Leave To File Second Amended Complaint (doc. #62) is DENIED.

The Cleveland Clinic Defendants and Intuitive offer several other reasons for denying the Antoons' Motion for Leave To File Second Amended Complaint. However, these reasons need not be and are not addressed.

### **MOTIONS TO DISMISS**

Because the Antoons have been denied leave to amend the Amended Complaint, the Motions To Dismiss the Amended Complaint made by the Cleveland Clinic Defendants (doc. #55) and Intuitive (doc. #54) must be addressed. These Motions are now fully briefed and ripe for decision.

At the outset, the Court notes that the Amended Complaint is filed pro se on behalf of David F. Antoon and Linda R. Antoon. (Doc. #4). However, the Amended Complaint is signed only by David Antoon. David Antoon, may, of course, bring a pro se complaint on behalf of himself, but he cannot bring a pro se complaint on behalf of another. Therefore, Linda R. Antoon could be dismissed as a relator for this action. However, counsel now having entered his appearance for the Antoons, the Court will consider these motions against both Antoons.

The Amended Complaint does not identify specific causes of action. It does, however, make certain assertions regarding violation of the FCA by Defendants Kaouk, Goel, Lee, Cosgrove, Cywinski, Feldman, Covin, Frost, DiCello, Henderson, Serkey, Goldman, Tucker and

Intuitive and violations of the Anti-Kickback statute by Kaouk, Goel, Cosgrove, Cywinski, Feldman, and Intuitive.

### **RELEVANT FACTUAL ALLEGATIONS FROM AMENDED COMPLAINT**

The factual allegations in the Antoons' Amended Complaint are the same as those in the proposed second amended complaint with the exceptions identified below. The factual allegations in the Antoos' Amended Complaint are viewed in a light most favorable to the Antoos for purposes of the Motions To Dismiss that are now being considered. Finally, since the paragraphs in the Amended Complaint are not numbered, reference will be to the page number of the Amended Complaint.

The proposed second amended complaint alleges that, on February 5, 2008, Kaouk and CCF submitted "Health Insurance Claim Form 1500" to the U.S. Government for reimbursement for services provided to Antoon and attaches a copy of a Form 1500. The Amended Complaint alleges that Kaouk "did submit CMS-1500 claim form, or like form...." but a copy of a specific form is not attached. (Am. Compl. p. 18.)

The proposed second amended complaint asserts that, on June 19, 2008, Antoon and his wife met with Kaouk and Mooney to discuss Antoon's lack of recovery, incontinence and impotence; that Kaouk suggested that Antoon remain positive and patient; and that Kaouk suggested that Antoon's lack of recovery was anxiety related. The proposed second amended complaint also identifies several alleged emails to Kaouk, Mooney and Tucker. Finally, the proposed second amended complaint asserts that Antoon and his wife again met with Kaouk on December 11, 2008.

No mention is made of these visits or emails in the Amended Complaint. Antoon does,

however, assert in the Amended Complaint that he returned to the Cleveland Clinic on January 15, 2010, and had his Jackson Pratt drain and Foley catheter removed. (Id.)

In the Amended Complaint, Antoon asserts that he filed complaints with various entities. The proposed second amended complaint provides additional details of these complaints and the results and identifies additional complaints and the results.

Unlike the proposed second amended complaint, Intuitive is mentioned only once in the Amended Complaint. Therein, the Antoons assert that Intuitive entered into a financial arrangement with Kaouk. Specifically, the Antoos allege that:

Intuitive knowingly and willfully paid remuneration directly or indirectly, overtly or covertly, in cash or in kind to Jihad Kaouk to induce Jihad Kaouk to recommend robotic surgery over other forms of surgery or treatment for which payment was made in part under TRICARE, a Federal health care program [and] induced Jihad Kaouk to provide falsely inflated positive outcomes to patients to encourage consent for such surgery with their product, the da Vinci robotic device.

There is some discrepancy between the proposed second amended complaint, the Amended Complaint and court records regarding the lawsuits that the Antoos filed. In the proposed second amended complaint, the Antoos allege that they filed their first qui tam suit pro se in February of 2010 and filed the original medical malpractice claim in Cleveland on June 6, 2010. No mention is made regarding these lawsuits in the Amended Complaint.

There is no record of the filing of the first qui tam action in February of 2010. Court records do, however, indicate that the Antoos filed what amounts to a medical malpractice action in the Court of Common Pleas for Cuyahoga County, Ohio, on June 1, 2010. Further, the case filed in the Cuyahoga Common Please Court was dismissed without prejudice by the Antoos pursuant to Ohio Civ. Rule 41(A) on June 13, 2011.

In the Amended Complaint, the Antoos assert that a review of multiple record sets by an

independent, uncompensated and board-certified urologist suggest that Antoon's treatment did not meet the standard of care and was potentially lethal. (Id. at 16.) Further, according to the Antoons, evaluations by board-certified urologists at V. A. hospitals in Dayton, Ohio, Iowa City, Iowa, and the University of Iowa have similar findings. No mention is made of these assertions in the proposed second amended complaint. Otherwise, for purposes of the Motions To Dismiss, the relevant factual allegations in the Amended Complaint and the proposed second amended complaint are the same.

### **ANALYSIS OF MOTIONS TO DISMISS**

The Cleveland Clinic Defendants and Intuitive offer several reasons to dismiss the Antoons' Amended Complaint. The Antoons oppose dismissal.

The Antoons' Amended Complaint could be read to assert two federal claims: violation of the FCA and violation of the Anti-Kickback Statute. Each of these two federal claims will first be analyzed because, without one of them, this Court does not have subject-matter jurisdiction.

#### **The FCA Claim**

##### **Rule 9(b) Particularity**

Rule 9(b) requires that Antoon's FCA claim be pled with particularity. Thus, under Rule 9(b), the Amended Complaint must allege the time, place and content of the alleged misrepresentation, the fraudulent scheme, the fraudulent intent of the defendants and the injury resulting from the fraud. Each of these requirements will be examined with regard to Antoon's Amended Complaint.

##### **Time, Place and Content of Alleged Misrepresentations**

In this case, the Antoons' Amended Complaint pleads that CMS-1500 claim forms are submitted to the Government by hospitals and physicians to obtain payments for services and that

certain named Defendants submitted CMS-1500 claim forms to the Government for payment. However, the Antoons' Amended Complaint does not identify the actual services that Antoon received and the specific claim form submitted for those services and the date the claim form or forms were submitted. Therefore, the Antoons' Amended Complaint does not allege the time, place nor content of any alleged misrepresentations.

The Antoons argue that Rule 9(b)'s pleading requirement should be relaxed in this case. The Sixth Circuit has determined that the requirement that a relator identify an actual false claim may be relaxed when a relator has pled facts which support a strong inference that a claim was submitted even though the relator is unable to produce an actual billing or invoice. *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 471 (6th Cir. 2011). The Sixth Circuit has further opined that such a strong inference may arise when the relator has "personal knowledge that the claims were submitted by the Defendants... for payment." *Id.* (citing *United States ex rel. Lane v. Murfreesboro Dermatology Clinic, PLC*, 2010 WL 1926131 at \*5 (E.D. Tenn. May 12, 2010)). In the examples cited by the Sixth Circuit in adopting this relaxed pleading standard, the personal knowledge was acquired by being a member of a billing department or personal discussions with an office administrator. *Id.*

However, the Antoons' Amended Complaint does not allege that Antoon had the personal knowledge that specific claims were submitted by certain Defendants for services provided to him. Therefore, this is not a situation where the relaxed pleading standards will be applied.

#### Fraudulent Scheme

In addition to satisfying the requirement that a claim be submitted, the Antoons must plead that the claim submitted was fraudulent or part of a fraudulent scheme. Antoons' Amended Complaint does not allege that any Cleveland Clinic Defendant or that Intuitive submitted a claim

that was factually false. Therefore, the Court must consider whether the Antoons allege that any of the alleged claims submitted were fraudulent under a false certification theory.

The Amended Complaint does not allege that Cleveland Clinic Defendants or Intuitive submitted any claims that were factually false. The Antoons respond that this complaint of a false claim is plainly directed against the Defendants in connection with the factual allegation that Kaouk was not present during the operation and was not present as required by the conditions for reimbursement under the TRICARE program.

However, this argument is without merit. First, while it may arguably be a factual allegation, it is not an allegation that the alleged claim is factually false, i.e. that Kaouk did not provide any service or that the services provided had no medical value. Further, the portions of the TRICARE Reimbursement Manual included in the Amended Complaint apply to teaching physicians. Yet the Amended Complaint does not plead that Kaouk was a teaching physician or that he sought reimbursement as a teaching physician. Finally, the Amended Complaint cites no condition of payment that would be violated if Kaouk was not present during the operation.

Therefore, the Court must consider whether the Amended Complaint alleges that the Cleveland Clinic Defendants or Intuitive falsely certified that they complied with a statute or regulation, the compliance with which is a condition for Government payment.

The Amended Complaint does not allege that Intuitive submitted any claim. Therefore, the Amended Complaint does not allege that Intuitive falsely certified anything. Further, the Amended Complaint does not allege that the Cleveland Clinic Defendants, Kaouk in particular, certified compliance with any law or regulation. *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1217 (10<sup>th</sup> Cir. 2008). As discussed above, the TRICARE Reimbursement Manual is not a law or regulation. In addition, the Amended Complaint does not

allege that any of the identified provisions had to be complied with as a prerequisite to the payment of a claim by the Government. Even if the provisions cited were conditions of payment, the Amended Complaint does not specifically plead how or when these alleged regulations were violated or by whom.

The FCA also forbids conspiracies. To plead an FCA conspiracy, a relator must allege: “(1) that there was a single plan to get a false claim paid, (2) that the alleged coconspirators shared in the general conspiratorial objective to get a false claim paid, and (3) that one or more conspirators performed an overt act in furtherance of the conspiracy to get a false claim paid.” *United States ex rel. Judd v. Maloy*, No. 3:03-cv-241, 2006 WL 2583318 at \*9 (S.D. Ohio Sep. 6, 2006)(citing *United States v. Murphy*, 937 F.2d 1032, 1038-39 (6<sup>th</sup> Cir. 1991)).

In this case, the Antoons’ Amended Complaint alleges none of these elements. Therefore, the Amended Complaint does not allege an FCA conspiracy with the required particularity.

#### Fraudulent Intent

Antoon’s Amended Complaint does not specifically aver that the Cleveland Clinic Defendants or Intuitive acted with intent. However, viewing the Amended Complaint in a light most favorable to Antoon, the Court can conclude that the false representations alleged in the Amended Complaint were intentionally made.

#### Resulting Injury

The Antoons allege that David Antoon underwent surgery on January 8, 2008, which resulted in multiple permanent injuries causing disability and loss of enjoyment. They do not, however, plead that these injuries were a result of a violation or violations of the FCA. Thus, Antoon has not pled that the alleged violations of the FCA resulted in injuries to David Antoon.

#### Conclusion Regarding Rule 9(b) Particularity

The Amended Complaint does not satisfy Rule 9(b)'s particularity requirement. The Amended Complaint does not allege the time, place and content of any alleged misrepresentation, the fraudulent scheme and the injury resulting from violation of the FCA.

### **Public-Disclosure Doctrine**

The public-disclosure provision of the FCA removes federal jurisdiction from FCA actions that are based upon the public disclosure of allegations in a criminal, civil or administrative hearing; in a congressional, administrative or Government Accounting Office report, hearing, audit or investigation; or from the news media. Public disclosure also includes documents that have been filed with a court and FOIA responses.

An “original source” is excepted from the public-disclosure bar. An original source is an “individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an FCA action.

In this case, the Antoons argue that they are the original source. The Cleveland Clinic Defendants and Intuitive argue that the public-disclosure provision applies and the Antoons are not an original source.

#### Intuitive

In the Amended Complaint, the Antoons allege that Intuitive entered into a financial arrangement with Kaouk that induced Kaouk to provide “falsely inflated positive outcomes to patients to encourage consent” for surgery using Intuitive’s da Vinci robotic device. Thus, the Antoons allege that (1) Intuitive had a financial arrangement and that (2) Kaouk provided “falsely inflated” positive outcomes to patients to encourage consent for using Intuitive’s robotic device.

The facts underlying both of these allegations were in the public domain before any of the

Antoons' complaints were filed. Previous patients have brought malpractice actions against Kaouk alleging that he falsely inflates the potential outcomes for robotic surgery and that he was paid by Intuitive, and the Antoons do not allege that they have independent knowledge regarding these allegations. *See, i.e. Gagliano v. Kaouk*, No. CV-09-707473 (Cuyahoga County, Ohio Ct. Com. Pl.)(complaint filed on Oct. 21, 2009). Further, there is evidence that Kaouk has authored publications on Intuitive's robotic surgery that disclose Kaouk's financial arrangements with Intuitive prior to when Antoon's lawsuits were filed.

([http://myclevelandclinic.org/staff\\_directory/staff\\_display.aspx?doctorid=4363](http://myclevelandclinic.org/staff_directory/staff_display.aspx?doctorid=4363).) Finally, dissatisfied patients have posted allegations online regarding the outcomes of Kaouk's robotic surgery. (<http://www.doctorsdig.com/dr-jihad-kaouk-review.html>, posted Aug. 18, 2011.)

The Antoons respond that David Antoon made his allegations to CMS, a federal agency, and that the matters of public record identified by Intuitive "are claims at a very high level of generality." However, neither of these arguments have merit.

First, the Antoons do not allege that he provided the information to the Government before the public disclosure. The Amended Complaint alleges that the Antoons provided "a statement of all material evidence and information related" to the claims simultaneous with the filing of the original and amended qui tam action. This was after public disclosure.

Second, the Antoons argue that David Antoon provided his allegations to CMS. However, the Amended Complaint does not assert that the Antoons provided the information to CMS. In fact, the fraud allegations in the Amended Complaint appear to be based upon information and records received from CMS.

Third, even if the Antoons provided the information to CMS, providing information to any federal agency does not satisfy the FCA requirement to provide information to the Government.

Disclosure to the Government for purposes of the FCA is interpreted to mean disclosure to the DOJ. See 31 U.S.C. §§ 3730(a) and 3730(b)(2); *United States ex rel. McKenzie v. BellSouth Telecommunications, Inc.*, 123 F.3d 935, 943 (6<sup>th</sup> Cir. 1997).

Fourth, the public records identified by Intuitive are not at such a high level of generality that they are not considered public disclosure. The allegations against Intuitive in the Amended Complaint are substantially similar to the public disclosure. The public disclosures allege that Kaouk falsely inflates the potential outcomes for robotic surgery and that he was paid by Intuitive.

In sum, the public disclosure bar removes this Court's jurisdiction over Antoons FCA allegations against Intuitive. Further, the Antoons have not shown that they are the original source of their FCA allegations against Intuitive.

#### The Cleveland Clinic Defendants

The Cleveland Clinic Defendants argue that the court-filings in the Antoons' state suit qualify as public disclosures for purposes of the FCA, and that the Antoons are not the original source. The Antoons respond that the Amended Complaint is not barred by the public disclosure rule because he qualifies as an original source since he directed his complaints of fraud first to the CMS, a Government agency.

On June 6, 2010, the Antoons filed a medical malpractice claim in the Cuyahoga County, Ohio Court of Common Pleas. The June 2010 medical malpractice claim alleges essentially the same facts as the Amended Complaint. For example, the state complaint alleges that Kaouk did not perform critical parts of the surgery, fraudulently told the Antoons that he would, and failed to disclose the risks of surgery. The filing of the June 2010 medical malpractice claim qualifies as a public disclosure.

Thus, this Court does not have jurisdiction over the Antoons' FCA claim unless the Antoons qualify as an original source. The Antoons qualify as an original source if they have direct and independent knowledge of the information on which the allegations are based and have voluntarily provided the information to the Government before filing an FCA action.

On February 1, 2010, the Antoons filed an FCA claim in this Court. The February 2010 qui tam action alleges that the Cleveland Clinic is using unsupervised residents to perform surgeries and attending physicians are falsely reported as being present. The February 2010 qui tam action was reviewed by representatives of the DOJ. Further, the Complaint in the 2010 qui tam action is not sealed. Thus, the allegations that Cleveland Clinic is using unsupervised residents to perform surgeries and attending physicians are falsely reported as being present were presented to the DOJ by Antoon prior to being disclosed in the June 2010 state lawsuit.

However, the Amended Complaint includes many additional allegations and there is no record that these additional allegations were presented to the Government before the Amended Complaint was filed. Therefore, the Court must consider whether the Antoons were the original source of these additional assertions.

The Antoons argues that David Antoon was the original source since he directed his complaints of fraud first to the CMS, a Government agency. However, as determined above, disclosure to the Government for purposes of the FCA is interpreted to mean disclosure to the Department of Justice. While there is evidence that the Antoons presented the fraud allegations to the DOJ at the time he filed his Complaint, there is nothing in the pleadings to indicate that the Antoons presented these fraud allegations to the Government before they filed their Complaint. Therefore, the pleadings do not show that David Antoon was an original source of the fraud allegations.

Because the fraud allegations were disclosed publically, at least at the time the Antoons filed their medical malpractice action in state court, and because David Antoon was not the original source of these fraud allegations, this Court does not have jurisdiction to entertain the FCA claims in the Amended Complaint.

### **The Anti-Kickback Claims**

The Antoons' Amended Complaint also alleges that Kaouk, Goel, Cosgrove, Cywinski, Feldman and Intuitive violated the Anti-Kickback statute. Thus, the Antoons must at least plausibly plead that these individuals and entity violated the Anti-Kickback statute.

The pleading in the Antoons' Amended Complaint that involve the Anti-Kickback Statute merely paraphrase the criminal provisions of the Anti-Kickback Statute. This pleading is unavailing for at least two reasons. First, the provisions of the Anti-Kickback Statute cited in the Amended Complaint are criminal provisions and, as such, may only be enforced by the Government. Second, merely paraphrasing a statute does not satisfy normal pleading standards.

Therefore, the Amended Complaint does not state a plausible violation of the Anti-Kickback Statute. Allegations in the Amended Complaint of violations of the Anti-Kickback Statute are dismissed.

### **Conclusion On Motions To Dismiss**

The Anti-Kickback claims in Antoons' Amended Complaint are dismissed because they do not plausibly plead violations of the Anti-Kickback Statute. Further, the Court does not have subject-matter jurisdiction to adjudicate the FCA claims. Finally, since no federal claims remain, the Court declines to exercise supplemental jurisdiction over any remaining claims in the Amended Complaint. The Cleveland Clinic Defendants' and Intuitive's Motions To Dismiss the Antoons' Amended Complaint (docs. 54 and 55) are GRANTED.

**DONE and ORDERED** in Dayton, Ohio this Fifteenth day of October, 2013.

**s/Thomas M. Rose**

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THOMAS M. ROSE  
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record